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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A01N 59/12, A61L 2/18 — A1

(11) International Publication Number: WO 95/12316

(43) International Publication Date: 11 May 1995 (11.05.95)

(21) International Application Number: PCT/GB94/02395

(22) International Filing Date: 2 November 1994 (02.11.94)

(30) Priority Data:
9322555.5 2 November 1993 (02.11.93) GB

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(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ).

Published
With international search report.

(54) Title: A STERILANT SOLUTION AND A METHOD OF STERILISING SURGICAL INSTRUMENTS

(57) Abstract

A method of sterilising surgical instruments at ambient temperatures comprises firstly washing the instrument with water and with a detergent liquid having bactericidal properties to remove blood, body fluid and/or body tissue adhering to the instrument and thereafter washing the instrument in a sterile aqueous solution of an iodate and iodide at a pH of from 3 to 5. Also provided is a sterilant liquid which is a sterile aqueous solution of an iodate and an iodide, preferably sodium iodate and potassium iodide, respectively, buffered at a pH of from 3 to 5.

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A STERILANT SOLUTION AND A METHOD OF STERILISING SURGICAL INSTRUMENTS

This invention relates to a sterilising system and in particular to a method and solution for sterilising surgical instruments at ambient temperature.

Several methods are already known for sterilising surgical instruments at ambient temperature. One such is described in WO 92/11875 where there is described and claimed a process for sterilising surgical instruments at ambient temperature characterised in that the process comprises the steps of firstly decontaminating the surgical instrument in a closed environment by washing it with water and with a detergent liquid having bactericidal properties to remove any blood, body fluid and/or body tissue adhering to the instrument, and secondly washing the instrument in said closed environment in a strongly bactericidal liquid to sterilise the instrument. Also described and claimed in WO 92/11875 is an apparatus suitable for use in the process for sterilising surgical instruments as described above which apparatus comprises a base unit having connected thereto a closed container for surgical instruments within which the surgical instruments are to be sterilised, said container having a fluid-tight lid, holding means for holding such surgical instruments, an inlet and an outlet for the detergent and sterilising liquids, venting means, pump means for pumping the detergent and sterilising liquids into and out of the container, and sensor and control means for controlling the order and amount of pumping.

The above mentioned process and apparatus provide a very effective means of sterilising surgical instruments, and in particular delicate surgical

instruments such as endoscopes, under ambient conditions so that the surgical instruments are not damaged by the high temperatures employed in conventional autoclaving sterilisation procedures.

As is explained in the above mentioned published patent specification, prior cold sterilising procedures have a number of disadvantages which the process and apparatus of the specification overcome.

The preferred strongly bactericidal liquid described for use in the second step of the above mentioned process is an iodine solution. Iodine solutions are in fact very effective sterilising media which can destroy all microbes.

There is the need for shorter sterilising cycles when using sterilising apparatus since the longer is the sterilising process the longer is the time during which the surgical instruments are unavailable for use, and an advantage of the method of the present invention is that it enables the sterilising procedure to take less time.

According to the present invention there is provided a method of sterilising surgical instruments at ambient temperatures which method comprises firstly washing the instrument with water, then with a detergent liquid having bactericidal properties to remove blood, body fluid and/or body tissue adhering to the instrument and thereafter washing the instrument in a sterile aqueous solution of an iodate and an iodide at a pH of from 3 to 5.

The present invention also provides a sterile aqueous solution of an iodate at a concentration of 0.1 M to 1 M and an iodide at a concentration of 0.01 M to 1 M buffered at a pH of from 3 to 5 for use as a sterilising liquid.

It should be appreciated that in practice the sterilising solution of the present invention will

usually be used in a sterilising process after the contaminated surgical instruments have already been washed by water and a detergent liquid to remove blood, body fluid and/or body tissue adhering to the instrument. Such detergent is preferably a solution of a quaternary ammonium compound such as Cetrimide, preferably in an amount of 0.07 to 5% by weight, typically a 1% aqueous solution. Cetrimide is a mixture of surface-active quarternary ammonium compounds which are C_{12}, C_{14} and C_{16} alkyltrimethylammonium bromides. The pH of such solution is not critical. However, as mentioned above, the pH of the sterilising liquid itself is important and must be in the range from 3 to 5, preferably at about 4 or 4.5. The pH is stabilised in this range by a suitable buffer, preferably an acetate buffer but any other suitable buffers may be used, such as a citrate/phosphate buffer.

The iodate used in the sterilising solution is preferably sodium iodate and its amount will preferably be in the range from 0.05 M to 0.5 M.

The iodide used in the sterilising solution is preferably potassium iodide which will be used in the range from 0.1 M up to 1 M or 0.5 M. This dissolves any free iodine produced when iodate reacts with iodide at an acid pH.

An example of a sterilising solution in accord with the present invention is a 0.3 M aqueous solution of potassium iodide containing 0.25 M sodium iodate and 0.1 M sodium acetate at a pH of 4.0. Another example of a sterilising solution in accord with the invention is a 0.3 M aqueous solution of potassium iodide containing 0.1 M sodium iodate and 0.1 M sodium acetate buffer at a pH of 4.5.

Some particular considerations need to be borne in mind when using the combination of sodium iodate

and potassium iodide in this invention.

Firstly, one of the primary aims is to produce a solution which has maximum oxidising potential and will also produce a high iodine concentration. The relevant reaction mechanisms are believed to be as follows:-

1) Iodate ions are reduced by reducing substances as follows:

$$IO_3^- + 6H^+ + 6e^- \longrightarrow I^- + 3H_2O;$$

2) Iodate and iodide ions react together to yield free iodine:

$$IO_3^- + 5I^- + 6H^+ \longrightarrow 3I_2 + 3H_2O;$$

and

3) Free iodine is oxidised by the iodate:

$$IO_3^- + 2I_2 + 6H^+ \longrightarrow 5I^+ + 3H_2O$$

However, the solubility of sodium iodate is relatively limited and there is a practical upper limit of about 0.5 M for sodium iodate. Undissolved sodium iodate is to be avoided and therefore the concentration of sodium iodate and the temperature of storage of the sterilant solution need to be so chosen as to avoid problems arising from lack of solubility, e.g. clogging of filters and change in the concentration, and therefore the effectiveness of the sterilant solutions.

Also iodine crystal formation must be avoided since this also may lead to such problems as clogging of filters. For any particular sodium iodate concentration there is a minimum concentration of potassium iodide to prevent iodine crystal formation. This minimum can be readily determined by routine tests.

In a typical sterilising method using the sterilant of the present invention the void space of the steriliser tray containing the surgical instrument(s) is filled with sterile water and then

emptied to be replaced by sterile air. The void space is then filled with 1% Cetrimide. This is achieved by mixing 19.5% Cetrimide (200 ml) with 3700 ml sterile water, and then emptying to be replaced by sterile air. The void space is then refilled with 1% Cetrimide and left to stand for 10 minutes before being drained and refilling with sterile air. Three successive washes with sterile water are then performed and each time the void space is allowed to fill with sterile air. The tray is then filled for example with 0.25 M sodium iodate in 0.1 M sodium acetate pH 4.0 also containing 0.3 M potassium iodide. This solution is retained for ten minutes before being drained to be replaced by sterile air. The tray is then filled with sterile water and finally emptied to be replaced with sterile air.

CLAIMS:

1. A method of sterilising surgical instruments at ambient temperatures which method comprises firstly washing the instrument with water, then with a detergent liquid having bactericidal properties to remove blood, body fluid and/or body tissue adhering to the instrument and thereafter washing the instrument in a sterile aqueous solution of an iodate and iodide at a pH of from 3 to 5.

2. A method as claimed in claim 1 wherein the iodate is sodium iodate.

3. A method as claimed in claim 1 or claim 2 wherein the concentration of iodate is from 0.01 M to 1M.

4. A method as claimed in claim 3 wherein the concentration of iodate is from 0.05 M to 0.5 M.

5. A method as claimed in any one of the preceding claims wherein the iodide is potassium iodide.

6. A method as claimed in any one of the preceding claims wherein the iodide is present in an amount of 0.01 M to 1 M.

7. A method as claimed in claim 6 wherein the concentration of iodide is from 0.03 M, preferably from 0.1 M up to 0.5 M, preferably up to 0.3 M.

8. A method as claimed in any one of the preceding claims wherein the detergent is a

bactericidal quaternary ammonium compound.

9. A method as claimed in claim 8 wherein the quarternary ammonium compound is Cetrimide.

10. A method as claimed in claim 8 or claim 9 wherein the quaternary ammonium compound is present in an amount of from 0.07% to 5%.

11. A method as claimed in any one of the preceding claims wherein the aqueous solution of iodate and iodide is buffered using an acetate buffer.

12. A sterile aqueous solution of an iodate at a concentration of from 0.01 M preferably from 0.05 M, to 1M and an iodide at a concentration of from 0.01 M to 1 M or 0.5 M, preferably to 0.3 M, buffered at a pH of from 3 to 5, for use as a sterilising liquid.

INTERNATIONAL SEARCH REPORT

Intern al Application No
PCT/GB 94/02395

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A01N59/12 A61L2/18

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A01N A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO,A,92 11875 (DUNCAN GROUP) 23 July 1992 see page 3, line 2 - line 35 see page 9, line 5 - line 27 see claims 1-6	1-12
Y	US,A,2 918 400 (A.C.LOONAM) 22 December 1959 see column 1, line 23 - line 42	1-12
Y	S.S.BLOCK 'Disinfection, Sterilization and Preservation' 1991 , LEA & FEBIGER , PHILADELPHIA, US Fourth Edition chapter 8: W.GOTTARDI 'IODINE AND IODINE COMPOUNDS', pages 152-166 see page 153, column 1, equation (7) see page 153, column 2, lines 10-11	1-12

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
1 February 1995	08. 02. 95
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Authorized officer Lamers, W

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C(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	CHEMICAL ABSTRACTS, vol. 96, no. 14, 5 April 1982, Columbus, Ohio, US; abstract no. 110083, W.GOTTARDI 'Formation of iodate as a reason for the decrease of efficiency of iodine-containing disinfectants' see abstract & ZENTRALBL. BAKTERIOL., MIKROBIOL. HYG., ABT.1, ORIG. B, vol.172, no.6, 1981 pages 498 - 507	1-12
A	CHEMICAL ABSTRACTS, vol. 110, no. 24, 12 June 1989, Columbus, Ohio, US; abstract no. 219077, see abstract & JP,A,63 068 508 (SHOWA) 28 March 1988	1-12
A	CHEMICAL ABSTRACTS, vol. 66, no. 15, 10 April 1967, Columbus, Ohio, US; abstract no. 64613x, J.BARTOS ET AL. 'The disinfectant effectiveness of a concentrate containing potassium hydrogen iodate, potassium iodide, and hydrochloric acid on Mycobacterium phlei' page 6055 ;column 1 ; see abstract & VET. MED, vol.39, no.12, 1966 pages 703 - 709	1-12

INTERNATIONAL SEARCH REPORT

information on patent family members

Intern al Application No
PCT/GB 94/02395

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WO-A-9211875	23-07-92	GB-A- 2251382	08-07-92
		AU-A- 1158492	17-08-92
		EP-A- 0566598	27-10-93
		JP-T- 6509482	27-10-94
US-A-2918400	22-12-59	NONE	
JP-A-63068508	28-03-88	NONE	

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